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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,657	RUNGE ET AL.	
	Examiner	Art Unit	
	Kortney L. Klinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's amendments and remarks filed 11/6/2008.

Claims 1-25, 27-31 and 33-36 were canceled.

Claims 37-62 were added and are pending.

Withdrawn Objections/Rejections

Specification Objections

The objection to the specification for improper use of trademarks is withdrawn in light of Applicant's amendments to the specification. All trademarks are now capitalized wherever they appear or include the appropriated trademark symbol and are accompanied by the generic terminology.

Claim Objections

The objection of claims 5-25 and 36 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, in the case of claim 5 and 36 and cannot depend from any other multiple dependent claim is rendered moot in light of the cancellation of these claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Neri et al. (US 4474813) is withdrawn in light of the cancellation of claims 1-4 and the submission of new claims with new claim limitations.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Neri et al. (US 3995060) is withdrawn in light of the cancellation of claims 1 and the submission of new claims with new claim limitations.

Claim Rejections - 35 USC § 103

The rejection of claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri (US 3995060) is withdrawn in light of the cancellation of claims 2-4 and the submission of new claims with new claim limitations.

New/Maintained Claim Rejections

Claim Objections

Claims 39 and 61-62 are objected to because of the following informalities: The word **mixer** is misspelled **mixture** in these claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the following limitation, "...wherein the flutamide particles comprise a mean particle size greater than the mean particle size of flutamide that, with an initial particle size of from 5 to 240 μm, has been subjected to a milling operation."

The sentence structure of the claim is unclear. It is unclear if the phrase "with an initial particle size of from 5 to 240 μm" refers to the particle size of the milled or to the unmilled flutamide.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the free acid amid form of flutamide, does not reasonably provide enablement for pharmaceutically acceptable solvates of flutamide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. The nature of the invention

2. The state of the prior art
3. The predictability or lack thereof in the art
4. The amount of direction or guidance present
5. The presence or absence of working examples
6. The breadth of the claims
7. The quantity of experimentation needed, and
8. The level of skill in the art

The nature of the invention and the breadth of the claims. The nature of the invention is drawn to a pharmaceutical formulation comprising free acid amide or pharmaceutically acceptable **solvate** of flutamide. The instant breadth of the rejected claims is broader than the disclosure, specifically; the instant claims include solvates of flutamide.

The state of the prior art and the predictability or lack thereof in the art. Active pharmaceutical ingredients are frequently delivered to the patient in the solid-state as part of an approved dosage form (e.g., tablets, capsules, etc.). Solids provide a convenient, compact, and generally stable format to store an active pharmaceutical ingredient or a drug product. Understanding and controlling the solid-state chemistry of active pharmaceutical ingredients, both as pure drug substances and in formulated products, is therefore an important aspect of the drug development process. Active pharmaceutical ingredients can exist in a variety of distinct solid forms, including polymorphs, solvates, hydrates, salts, co-crystals, and amorphous solids. Each form displays unique physicochemical properties that can profoundly influence the bioavailability, manufacturability purification, stability, and other performance characteristics of the drug. Hence, it is critical to understand the relationship between the particular solid form of a compound and its functional properties.

For ionizable compounds, preparation of salt forms using pharmaceutically acceptable acids and bases is a common strategy to improve bioavailability. However, the preparation of other solid forms such as polymorphs and solvates are not so common as to be predictable. In order to obtain patent protection on these forms, some of which may have significantly different properties and relevance as development candidates, it is essential to prepare them, identify conditions for making them, and evaluate their properties as valuable new pharmaceutical materials. A large number of factors can influence crystal nucleation and growth during this process, including the composition of the crystallization medium and the processes used to generate super-saturation and promote crystallization Morissette et al. ("High-throughput crystallization: polymorphs, salts, co-crystals and solvates of pharmaceutical solids" *Advanced Drug Delivery Reviews,* **2004**, *56*, 275-300). For these reasons, the state of the prior art is one of unpredictability.

As stated above, crystalline solids can exist in the form of polymorphs, solvates or hydrates. "Phase transitions such as polymorph interconversion, desolvation of solvate, formation of hydrate, and conversion of crystalline to amorphous form may occur during various pharmaceutical processes, which may alter the dissolution rate and transport characteristics of the drug. It is therefore desirable to choose the most suitable and stable form of the drug in the initial stages of drug development" Vippagunta et al. ("Crystalline solids" *Advanced Drug Delivery Reviews*, **2001**, *48*, 3-26, specifically see the abstract). In further discussing the predictability of the formation of solvates, Vippagunta disclose that "predicting the formation of solvates or hydrates of a

compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds" (page 18, section 3.4). Furthermore, "[o]ne can say that if the formation of polymorphs is a nuisance for crystal engineers, solvate formation can be a nightmare, because it is extremely difficult to *predict* whether a new species may crystallizes from solution with one or more molecules of solvent." Braga et al. ("Making crystals from crystals: a green route to crystal engineering and polymorphism" *Chem. Commun*. **2005**, 3635-3645, see p. 3640, 2nd column).

The state of the art also is such that solvates and hydrates are different chemical materials with different chemical identifiers (i.e. CAS registry numbers, molecular formulas, etc.). In this day and age, there is no reason why a chemist, or applicant, is unable to identify a particular chemical species. "Now, as there should never be any doubt, in this century, about the chemical identity of a material, then it follows that solvates of a compound can never be *pseudo*polymorphs, as there will **never** be any doubt as to their chemical identity. To draw a parallel in the art world, we could call a forgery of Van Goh's "Sunflower", if we so desired, a *pseudo*-"Sunflowers"-it would be false or spurious, and is similar enough to the original to be mistaken for it. But, we could not describe a fake "Mona Lisa" as a *pseudo*-"Sunflowers", despite being false, as there was never any possibility of mistaking one for the other." (Seddon et al. "*Pseudo*polymorph: A Polemic" *Crystal Growth and Design*, **2004**, *4*, 1087).

The Amount of Direction or Guidance Present and Presence or Absence of

Working Examples. The only direction or guidance present in the instant specification is for the free acid amide form of flutamide which is crystalline and/or amorphous. There is no data present in the specification for the preparation of solvates of flutamide. The specification only discloses that "flutamide may be used in the form of the free acid amide and/or one of its solvates" (page 8). Additionally, preferred embodiments and examples do not support enablement for solvates of flutamide. Finally, there are no working examples present in the disclosure for the preparation of solvates of flutamide. In each of the working examples, the free acid amide form of flutamide is recited.

The Quantity of Experimentation Needed and the Level of Skill in the Art. While the level of skill in the pharmaceutical arts is high, it would require undue experimentation for one of ordinary skill in the pertinent art to prepare *any* solvate of flutamide. The science of crystallization has evolved such that, without guidance or working examples in the specification, the claims lack enablement. This rejection can be overcome by deletion of the words "or a pharmaceutically acceptable solvate" from claim 50.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-40, 42-43, 47-48, 50-62 are rejected under 35 U.S.C. 102(b) as being anticipated by James et al. (US 6228401, as per Applicant's IDS).

It is important to note that the phrases "unmilled" with respect to flutamide and "wherein the flutamide has been subjected to intensive mixing in a forced-action mixture [mixer] with the at least one surface-active substance" of claim 37 and "wherein the formulation is mixed in a forced-action mixture [mixer] for 1 to 180 minutes" or claim 61 and "wherein the formulation is mixed in a forced-action mixture [mixer] for 3 to 60 minutes" are recitations of product-by-process limitations. Since claim 37 is a product-by-process claim, and all pending claims depend from claim 37, therefore, all pending claims are product-by-process claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). For more information regarding product-by-process claims, please refer to MPEP 2113. In the instant case, the claims are drawn to a pharmaceutical formulation comprising crystalline and/or amorphous flutamide particles mixed with at least one surface-active substance (claim 37). These features, as well as limitations imparted by subsequent dependent claims are taught by James et al., see below.

James et al. teach a pharmaceutical formulation comprising crystalline and/or amorphous flutamide particles mixed with at least one surface-active substance (Examples 6, 7, and 9). James does not explicitly state that the flutamide is crystalline and/or amorphous, however, because there are no other known forms that flutamide can be in, it must be crystalline and/or amorphous. The surface active substance is sodium lauryl sulfate which is an anionic compound as per claim 51. Sodium lauryl sulfate is the common name for sodium dodecylsulfate, as required by claim 52. James teaches that rotary cutters are one means of achieving the desired flutamide particle size (col. 2, lines 37-38). Rotary cutters are a type of forced-action mixer; the blades are forced through the desired mixture.

With respect to claims 38, 40 and 56, James teaches the formulation in the form of a tablet with at least one flow regulator (silica) in example 7. The tablet of example 7 could also be used as a suppository. The term suppository is an intended use and because the prior art structure is capable of performing the intended use, it meets the limitations of the claim, absent evidence to the contrary. With particular respect to claim 56, a tablet is considered a shaped article.

With respect to claim 39, James teaches the formulation as filling for capsules in examples 6 and 9.

With respect to claim 42, in light of the 112 2nd rejection, James teaches that post granulation milled flutamide results in particle size from 5 to 240 μ. Prior to milling, the particles would necessarily have a particle size greater than this.

With respect to claim 43, James teaches the X_{50} value of the flutamide particles is greater than 20 μm (example 5, column 7, see example 3 from the table at lines 45-47, X_{50} = 20.99 μm).

With respect to claims 47-48 which specify the specific surface area of the flutamide particles, James teaches a specific surface area of 0.47 m^2/cm^3 (example 5, column 7, see example 3 from the table at lines 45-47).

With respect to claim 50, James teaches the flutamide is in the form of its free acid amide or a pharmaceutically acceptable salt thereof (col. 2, lines 4-5).

With respect to claims 53-55 which specify the weight ratio of flutamide to surface-active substance, James teaches a ratio of flutamide to surface-active substance of 10.4 to 1 which falls within, and thereby anticipates the ranges for claims 53-55 (Example 6).

With respect to claims 57-59 which specify the amount of flutamide in the formulation, James teaches 125 mg of flutamide in the formulation which falls within and thereby anticipates the amounts claimed (Example 6).

With respect to claim 60, all of the working examples of James comprise at least one excipient selected from inorganic fillers, organic fillers, binders, glidants, lubricants, flow regulators and disintegrants. See particularly Example 6 which further comprises lactose, povidone, corn starch, magnesium stearate and water in addition to flutamide and the surface-active substance sodium lauryl sulfate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. (US 6228401, as per Applicant's IDS).

The teachings of James et al. are set forth above. In addition to that just discussed above, James also teaches that flutamide is relatively insoluble (col. 1, line 38) and that flutamide has a consistency which is difficult to mill due to the fact that it readily agglomerates and give inconsistent results (col. 2, lines 46-48).

James teaches that the specific surface area of flutamide is *critical* for determining bioavailability of flutamide (col. 1, lines 52-54). James also teaches that the range of particle sizes contained in a sample of flutamide influences the bioavailability and thus the therapeutic benefit of the drug (col. 2, lines 17-20). With respect to claim 44, James teaches that the X_{50} for the particles is less than 26.0 μ (col. 2, lines 23-24). With respect to claims 45-46, James teaches that the X_{90} value for the particles is from about 10 to about 130.0μ (col. 2, lines 28-29). With respect to claim 49 which specifies that the flutamide particles have specific surface area of 0.35 m^2/cm^3, James teaches flutamide particles having a specific surface area of at least about 0.35 m^2/cm^3. About 0.35 m^2/cm^3 overlaps with and thereby makes obvious the claimed value of less than 0.35 m^2/cm^3. Means of achieving these particle sizes, distributions and surface areas include milling, but also the use of rotary cutters (i.e. forced-action mixer), see col. 2, lines 37-38. Also, as addressed above, James teaches that particles of flutamide are known that range from 5 to 240 microns in size (col. 1, line 47). In view of the "about" language used by James with respect to the particle size ranges, and specific surface areas, it is the position of the Examiner that the ranges discussed in James, overlap and thereby make obvious those ranges of the instant claims. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to

arrive at particles with an X_{50} value greater than 26 microns and X_{90} values greater than 60 microns or 130 microns and particles with a specific surface area of less than $0.35m^2/cm^3$ based on the teachings of James at the time of the instant invention with a reasonable expectation of success. One would have been motivated to do so because James teaches X_{50} and X_{90} values and specific surface areas that overlap with, or are very close to those ranges claimed by applicant. Furthermore, James teaches that flutamide is known to exist in particle sizes up to 240 microns and also teaches that it is known in the art to achieve similar particle sizes, as measured by X_{50} and X_{90} values, and different specific surface areas by using rotary cutters or other milling techniques. One needs to merely adjust the speed of the mill or cutter and the amount of flutamide fed into the machine and/or the grinding period (col. 2, lines 39-42). Furthermore, because bioavailability is know to be critically dependent upon both the particle size distribution and the surface area of the resultant particles, one would be particularly motivated to play with both of these features in order to arrive at a set of flutamide particles with optimal bioavailability. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over James et al. (US 6228401) in further view of Neri et al. (US 3995060), both as per Applicant's IDS.

The teachings of James et al. are set forth above. James fails to explicitly teach that the flutamide has been subjected to recrystallization as necessitated by claim 41. Neri '060 teaches pharmaceutical formulations comprising flutamide (4-nitro-3-trifluoromethylisobutyranilide), which is necessarily either crystalline and/or amorphous, sodium lauryl sulfate (a surface-active substance) which are mixed in a bowl (column 17, lines 14-16). The mixture is not milled until subsequent steps (see column 17, lines 17-20). Furthermore, step 3 (lines 21-23) admits that the first milling contains unmilled fractions of flutamide and sodium lauryl sulfate. Neri teaches that recrystallization is a common and effective means of purifying flutamide (col. 2, line 37).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention based on the combined teachings of James and Neri to arrive at the instant formulation comprising recrystallized flutamide with a reasonable expectation for success. One would have been motivated to do so because Neri teaches that recrystilization is a common means of purifying flutamide. Since the desired composition is for pharmaceutical use, one would be particularly motivated to have a pure substance. The more pure the drug, in this case flutamide, the fewer chances for undesired side-effects.

Applicant's data in the specification has been considered. The pharmaceutical formulations shown in working examples 1 through 6 all consist of ingredients identical to those shown in the working examples of James et al., namely flutamide, lactose, sodium lauryl sulfate (a.k.a. sodium dodecylsulfate), microcrystalline cellulose, corn (maize) starch, silica and magnesium stearate. Example 1 contains crystalline, unmilled flutamide and was intensively mixed for 3 minutes in a forced-action mixer. Subsequent examples use either crystalline unmilled flutamide, micronized flutamide. Different mixing mechanisms are used, including a forced-action mixer, a free fall mixer etc. As taught in James, several different known milling and mixing all techniques give rise to different particle sizes, size distribution and surface areas, and these particle qualities can be easily manipulated by adjusting the speed of the mill, the amount of flutamide fed into the mill and the grinding period. Applicant's specification provides no examples exhibiting any results that would be unexpected from the teachings of the prior art.

Response to Arguments

Applicant's arguments submitted 11/6/2009 with respect to the rejection of claims 1-4 in view of Neri (US 4474813) and (US 3995060) have been fully considered, but are moot in light of the new grounds of rejection and the fact that all original claims were canceled.

Conclusion

Claims 37-62 are rejected. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611